

Longitudinal Assessment of Bariatric Surgery (LABS)

U.S. Department of Health and Human Services

NATIONAL INSTITUTES OF HEALTH

NIDDK NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES



What is the Longitudinal Assessment of Bariatric Surgery (LABS)?

The Longitudinal Assessment of Bariatric Surgery was originally known as the Bariatric Surgery Clinical Research Consortium. LABS is a National Institutes of Health (NIH)-funded consortium of six clinical centers and a data coordinating center working in cooperation with NIH scientific staff to plan, develop, and conduct coordinated clinical, epidemiological, and behavioral research in bariatric surgery.

What is bariatric surgery?

Bariatric surgery restricts stomach size and/or leads to decreased absorption of nutrients. These procedures can have dramatic health benefits, such as improved control of blood sugar or even reversal of type 2 diabetes, but they also carry substantial risks, including death.

How many people have had bariatric surgery?

According to the American Society for Bariatric Surgery (ASBS), the number of procedures increased from about 16,000 in the early 1990s to more than 103,000 in 2003.

Why did the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) launch LABS?

- A majority of U.S. adults are overweight or obese, with more than 30 percent of adults considered obese (Body Mass Index [BMI] greater than 30). An increasing number of adults are considered extremely obese (BMI greater than or equal to 40).

- Numerous studies have shown that behavioral therapy to improve diet and physical activity can lead to weight loss of approximately five to ten percent over four to six months.
- When a person loses weight, obesity-related conditions such as high blood pressure and type 2 diabetes improve, but if a person regains weight, these benefits are lost.
- In many cases, a person who regains weight ends up weighing more than he or she weighed before the intervention. Doctors need effective weight-loss methods for people with extreme obesity and effective ways to maintain long-term weight loss.
- Currently, the most effective means of losing substantial weight and maintaining that weight loss is through bariatric surgery.
- Although an increasing number of persons with extreme obesity are undergoing bariatric surgical procedures, there has been little systematic research to help determine its risks and benefits or to provide guidance on appropriate patient selection. To facilitate research in this area, NIDDK established LABS.

What is the goal of LABS?

LABS has brought together experts in bariatric surgery, obesity research, internal medicine, endocrinology, behavioral science, outcomes research, epidemiology, and other relevant fields to plan and conduct studies that will analyze the risks and benefits of bariatric surgery and its impact on the health and well-being of patients with extreme obesity, and identify the kinds of patients who are most likely to benefit.

How will LABS accomplish its goal?

The consortium has developed a database for collecting standardized information on patients undergoing bariatric surgery at the participating clinical centers. Rigorously collected information on patient characteristics, types of surgery, medical and psychosocial outcomes, and economic factors will ultimately provide science-based information on the risks and benefits of bariatric surgery. This information should lead to rational recommendations for clinical care.

LABS will also support clinical studies that are proposed, designed, and approved by the Steering Committee (see below). Examples of the types of questions that might be addressed by such studies include:

- The impact of surgical procedures on conditions such as insulin resistance and type 2 diabetes.
- The mechanisms by which bariatric surgery may enhance long-term weight maintenance.
- The causes of and potential treatments for obesity. For example, examining the impact of restrictive (laparoscopic banding) versus malabsorptive (gastric bypass or biliopancreatic diversion) surgical procedures on hormones presumed to affect appetite may provide insights leading to new, non-surgical obesity treatments that mimic the appetite-suppressive effects of surgery.

LABS Centers will also collect data and specimens for future research. These data will provide a valuable resource for the future study of obesity and its complications.

How is LABS organized?

- Through a competitive, peer-reviewed process, principal investigators at six clinical centers and a data coordinating center were funded in September 2003. These investigators are listed on page 3.
- The principal investigators at the clinical centers and data coordinating center and the NIH project scientist comprise the Steering Committee, which is the governing body for the consortium.

- The Steering Committee has met on a frequent basis to develop the database and plan the clinical protocols.
- Investigators, scientists, and clinicians from the participating centers with relevant expertise are participating in ongoing committees and working groups.

What is the study timeline for LABS?

- LABS was funded in September 2003.
- During the first 18 months, investigators have worked together to develop the database, plan the clinical protocols, and obtain appropriate human subjects approval. The LABS database started enrolling patients in March 2005.
- LABS will conduct one or more studies each year during its five-year funding period, ranging from small pilot studies to larger studies.
- Short-term and longer-term studies will be carried out during years 2-4, with continued follow-up and study analysis during the final year.

What funds are available for LABS?

LABS is funded at 3 million dollars per year for five years, for a total of 15 million dollars. There are also opportunities for investigators to apply for additional funding for ancillary studies through a request for applications (RFA). Information on the ancillary studies RFA is at:

<http://grants2.nih.gov/grants/guide/rfa-files/RFA-DK-03-022.html>.

The Office of Research on Women's Health (ORWH) provided funds to be used for LABS research related to women's health issues. Information on the ORWH can be found at: <http://www4.od.nih.gov/orwh/>.

Will LABS provide free bariatric surgery for study participants?

No. LABS cannot cover the costs of bariatric surgery or patient care. Study participants must be able to support the cost of their surgery and related patient care through medical insurance or other means. However,

any tests or examinations done solely for research purposes rather than routine patient care will be done at no cost to participants.

How can patients get more information about enrollment in LABS?

For more information about enrollment in LABS, see: <http://www.niddklabs.org>.

In what other ways might LABS help to advance future obesity research?

- LABS may provide the preliminary data needed for future investigator-initiated research on bariatric surgery and obesity. For example, if LABS investigators are able to identify metabolic and endocrine changes that take place after bariatric surgery, this information would allow researchers to submit independent applications for full-scale clinical studies.
- LABS may encourage researchers to study the causes and treatments of obesity and its related health problems by providing access to laboratory specimens and tissues.
- The presence of coordinated obesity research efforts at participating institutions may provide opportunities for research and clinical training to students in the health professions, as well as to young investigators.
- Information on the types of data being collected in the LABS database (not individual patient information) will be available on the LABS website, so that other interested clinicians and researchers can collect similar data on their patients, facilitating additional research on bariatric surgery.

LABS Principal Investigators at the Six Clinical Centers

Paul D. Berk, MD
Professor of Medicine
Columbia University
Medical Center
630 W. 168th Street
P.O. Box 83 BB912
New York, NY 10029-6574

Anita P. Courcoulas, MD
Director, Minimally Invasive Bariatric and
General Surgery
University of Pittsburgh Medical Center
Division of Thoracic and Foregut Surgery
5200 Centre Avenue, Suite 715
Pittsburgh, PA 15232

David R. Flum, MD, MPH, FACS
University of Washington
1950 NE Pacific Street
Box 356410
Seattle, WA 98195-6410

James E. Mitchell, MD
University of North Dakota
Neuropsychiatric Research Institute
120 8th Street South, 2nd Floor
Box 1415
Fargo, ND 58107

Walter J. Pories, MD, FACS
Professor of Surgery and Biochemistry
Brody School of Medicine
East Carolina University
600 Moyer Boulevard
Greenville, NC 27858

Bruce M. Wolfe, MD
Oregon Health and Science University
Division of General Surgery—BTE223
3181 S.W. Sam Jackson Park Road
Portland, OR 97239-3098

Data Coordinating Center

Steven H. Belle, PhD, MScHyg
Professor of Epidemiology and
Biostatistics
Data Coordinating Center
University of Pittsburgh
504 Parran Hall
130 Desoto Street
Pittsburgh, PA 15261

NIDDK Project Scientist

Carolyn W. Miles, PhD
Director, Clinical Obesity and Nutrition Program
Division of Digestive Diseases and Nutrition
NIDDK
NIH
6707 Democracy Blvd.
Room 665, MSC 5450
Bethesda, Maryland 20892-5450

For Further Information:

For additional assistance with media queries, including a list of LABS investigators with specific expertise in topics related to bariatric surgery, contact: Ms. Leslie L. Curtis, (301) 496-3585, NIDDK Office of Communications and Public Liaison, (301) 496-3583, curtisl@extra.nidk.nih.gov. For more information about LABS, see: <http://www.niddklabs.org>.

For general information about bariatric surgery, obesity, and related topics, contact:

The Weight-control Information Network (WIN)
1 WIN Way
Bethesda, Maryland 20892-3665
Phone: (202) 828-1025; Toll-free: 1-877-946-4627
<http://www.win.niddk.nih.gov>

The National Heart, Lung, and Blood Institute
Information Center
P.O. Box 30105
Bethesda, Maryland 20824-0105
Phone: 1-800-575-9355
<http://www.nhlbi.nih.gov>

For information about obesity research at NIH, see:

<http://www.obesityresearch.nih.gov>

To view general information about bariatric surgery, see:

<http://www.win.niddk.nih.gov/publications/gastric.htm>

<http://www.asbs.org> (This site is not affiliated with the NIH.)

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